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DOCKET NO.: TJU-2415

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman, et al.

Serial No.: 09/819,248

Filing Date: March 27, 2001

Group Art Unit: 1645

Examiner: Not Yet Assigned

USE OF EXPRESSION PROFILING FOR IDENTIFYING MOLECULAR

MARKERS USEFUL FOR DIAGNOSIS OF METASTATIC CANCER

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Assistant Commissioner for Patents Washington DC 20231

Dear Sir:

For:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

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There are no listed references which are not in the English language.

Examiner's request.

Date: 14 Dre 2001

Ellen M. Klann

Registration No. 44,836

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		of Patent and Publications Cited by Applicant everal sheets if necessary)			CENTER 1	JAN 2 2 2		
		Department of Commerce nt and Trademark Office	Filing Date March 27, 2001	Group 1645	00/2900	2002		
	OTH	ER DOCUMENTS (Including Aut	hoi	, Title, Date, Pertine	nt Pages, Etc	.)		
	AA	Abati and Liotta, "Looking forwar	d i	n diagnostic pathology	", Cancer, 19	996, 7	8, 1-3	
	AB	Adams, M.D. et al., "Serial analys 1996 , 18, 261-262	Adams, M.D. et al., "Serial analysis of gene expression: ESTs get smaller", <i>Bioessays</i> , 1996, 18, 261-262					
*	AC	Ausubel, et al., "Current protocols in Molecular Biology," John Wiley & Sons, Inc., NY, 2000					Inc.,	
*	AD	Ausubel, et al., "Current protocols in Molecular Biology," John Wiley & Sons, Inc., NY, 1999						
	AE	AE Bach, I., et al., "Cloning of human hepatic nuclear factor 1 (HNF1) and chromosomal localization of its gene in man and mouse", <i>Genomics</i> , 1990 , 8, 155-164 AF Barnes, W.M, "PCR amplification of up to 35-kb DNA with high fidelity and high yield from bacteriophage templates", <i>Proc. Natl. Acad. Sci. USA</i> , 1994 , 91, 2216-2220					osomal	
	AF							
	AG Beck, F. et al., "Reprogramming of intestinal differentation and intervalary regeneration in Cdx2 mutant mice", PNAS, 1999, 96, 7318-7323							
	АН	Brenner, S. et al., "Gene expression analysis by massively parallel signature sequencing (MPSS) on microbead arrays", <i>Nature Biotech.</i> , 2000 , <i>18</i> , 630-634						
	AI Carrithers, et al., "Guanylyl cyclase C is a selective marker for metastatic colorectal tumors in human extraintestinal tissues", <i>Proc. Natl Acad Sci. USA</i> , 1996 , <i>93</i> , 14827-14832							
	AJ Chartier, F.L., et al., "coning and sequencing of cDNAs encoding the human hepatocyte nuclear factor 4 indicate the presence of two isoforms in human liver" <i>Gene</i> , 1994 , <i>147</i> , 269-272					er''		
EXAN	MINER			DATE CONSIDER	ED			

^{*} A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



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	of Patent and Publications Cited by Applicant several sheets if necessary)	Applicant Scott A. Waldman,	ECH CENTER 1600 2900	2 2 2002			
	Department of Commerce nt and Trademark Office	Filing Date Group March 27, 2001 1645					
ОТН	ER DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.)				
AK	Chawengsaksophak, et al., "Homeos Nature, 1997, 386, 84-87	is and intestinal tumou	rs in Cdx2 mut	ant mice	,,		
AL	Cheng,S. et al., "Effective amplificate human genomic DNA", <i>Proc. Natl.</i>			s and			
AM	Cheung, V.G. et al., "Making and rea (Suppl.), 15-19	ding microarrays", Na	ture Genetics,	1999, <i>21</i>	,		
AN		Diatchenko, L. et al., "Suppression subtractive hybridization: A method for generating differentially regulated or tissue-specific cDNA probes and libraries", <i>Proc. Natl. Acad. Sci. USA</i> , 1996 , <i>93</i> , 6025-6030					
AO	Endege, W.O. et al., "Representative expression profiling", Biotechniques						
AP	Gurskaya, N.G. et al., "Equalizing cl of polymerase chain reaction:Clonin phytohemaglutinin and phorbol 12-n 90-97	g of jurkat cell transcri	pts induced by				
AQ	Gygi, S.P. et al., "Quantitative analysis of complex protein mixtures using isotope-coded affinity tags", <i>Nature Biotech.</i> , 1999 , <i>17</i> , 994-999						
AR	Gygi, S.P.et al., "Measuring gene expression by quantitative proteome analysis", Curr. Opinion in Biotech, 2000, 11, 396-401						
* AS	Hames, et al., "Gene Transcription: A Practical Approach," The practical Approach Series, New York: Oxford University Press, 1993			h			
AT	Heinemeyer, T.et al., "Databases on and COMPEL", Nucleic Acids Res.,	-	on: TRANSFA	.C, TRRI	D		
EXAMINER		DATE CONSIDER	ED				

^{*} A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.

Sheet 3 of 5 TO-1449 Modified Serial No. Docket No. TJU-2415 09/819,248 List of Patent and Publications **Applicant** Scott A. Waldman, et al. Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Filing Date Group Patent and Trademark Office March 27, 2001 1645 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	AU	Hou, J., et al., "Identification and purification of human stat proteins activated in responses to interleukin-2", <i>Immunity</i> , 1995 , 2, 321-329				
:	AV	Kritis, A.A., et al., "Isolation and characterization of a third isoform of human hepatocyte nuclear factor 4", <i>Gene</i> , 1996, 173, 275-280				
AW Kroczek, J., "Southern and Northern analysis", Chromatog, 1993, 618, 133-14						
AX Liang, P. et al., "Differential display of eukaryotic messenger RNA by means of polymerase chain reaction", <i>Science</i> , 1992 , <i>257</i> , 967-970						
	AY	Lie, Y.S. et al., "Advances in quantitative PCR technology: 5' nuclease assays", <i>Curr. Opin. Biotech.</i> , 1998 , <i>9</i> , 43-48				
	AZ Liefers, et al., "Micrometastases and survival in stage II colorectal cancer" <i>J. Med.</i> , 1998 , <i>339</i> , 223-228					
	BA	Lin, X., et al., "Characterization and sequence analysis of the human homeobox-containing gene GBX2", <i>Genomics</i> , 1996 , <i>31</i> , 335-342				
	ВВ	Mallo, G.V., et al., "Molecular cloning, sequencing and expression of the mRNA encoding human Cdx1 and Cdx2 homeobox. Down regulation of Cdx1 and Cdx2 mRNA expression during colorectal carcinogenesis", <i>Int. J. Cancer</i> , 1997 , <i>74</i> , 35-44				
	ВС	Mann, E.A et al., "Cell line-specific transcriptional activation of the promoter of the human guanylyl cyclase C/heat-stable enterotoxin receptor gene", <i>Biochem. Biophys Acta</i> , 1996 , 1305, 7-10				
	BD	O'Farrell, P.H., "High resolution two-dimensional electrophoresis of proteins", <i>J. Biol. Chem.</i> , 1975 , <i>250</i> , 4007-4021				

EXAMINER

DATE CONSIDERED

Form	PTO-1449 Modified	Docket No. TJU-2415	Serial No. 09/819,248	包	
	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Scott A. Waldman,	et al.	TECH CENTER 1600/2900	JAN 2 2 2002
	Department of Commerce at and Trademark Office	Filing Date March 27, 2001	Group 1645	1600/29	2002
ОТНЕ	ER DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)) 9	
BE	Patterson, S.D. et al., "Mass spectron seprated proteins", <i>Electrophoresis</i> ,		ne identificatio	n of gel-	,
BF	Pearson-white, S.H., "Human MyoD Nucleic Acids Res., 1991, 19, 1148	cDNA and deduced a	mino acid sequ	ience"	
BG	Pierrou, S., et al., "Cloning and characterization of seven human forkhead proteins:binding site specificity and DNA bending", <i>EMBO J.</i> , 1994 , <i>13</i> , 5002-5012				
ВН	Quandt, K. et al., "Matind and matinspector:new fst and versatile tools for detention of consensus matches in nucleotide sequence data", <i>Nucleic Acids Res.</i> , 1995, 23, 4878-4884				
BI	Schena, M. et al., "Quantitative monitoring of gene expression patterns with a complementary DNA microarray, <i>Science</i> , 1995 , <i>270</i> , 467-470				
ВЈ	BJ Shalon, D. et al., "A DNA microarray system for analyzing complex DNA samples using two-color fluorescent probe hybridization", <i>Genome Res.</i> , 1996 , <i>6</i> , 639-645				
BK	BK Sloan, J.P., "Molecules and micrometastases", Lancet, 1995, 345, 1255-1256				
BL	BL Spinella, D.G. et al., "Tandem arrayed ligation of expressed sequence tags (TALEST): a new method for generating global gene expression profiles", <i>Nucleic Acids Res.</i> , 1999, 27, e22 (I-VIII)				
ВМ	Stoffel, M., et al., "Localization of human homeodomain transcription factor insulin promoter factor 1 (IPF1) to chromosome band 13q12.1", <i>Genomics</i> , 1995, 28, 125-126				
BN	Suh, E. et al., "A homeodomain protegene transcription", Mol Cell. Biol.,	·	gulates intestin	ie-specif	ic
EXAMINER		DATE CONSIDER	ED		

	276, 1268-1272							
	BX	Biotechnology, 1999, 10, 465-469 Zhang, L. et al., "Gene expression profiles in normal and cancer cells", Science, 1997,						
	BW	Yeager, T.R. et al., "Constructing immortalized human cell lines" Curr. Opin.						
	BV	Wu, W., et al., "Mutations in PROP1 cause familial combined pituitary hormone deficiency", Nat. Genet, 1998, 18, 147-149						
	BU	Welsh, J. et al., "Arbitrarily primed PCR fingerprinting of RNA", <i>Nucleic Acids Res.</i> , 1992 , 20, 4695-4970						
	ВТ	Wang, M., et al., "The LIM domain homeobox gene <i>isl-1</i> : Conservation of human, hamster, and rat complementary deoxyribonucleic acid sequences and expression in cell types of nonneuroendocrine lineage", <i>Endocrinology</i> , 1994 , <i>134</i> , 1416-1422						
	BS	Wang, A. et al., "Rapid analysis of gene expression (RAGE) facilitates universal expression profiling", <i>Nucleic Acids Res.</i> , 1999 , <i>27</i> , 4609-4618						
	BR	Waldman, S.A. et al., "Heterogeneity of guanylyl cyclase C expressed by human colorectal cancer cell lines in vitro", <i>Cancer Epidemiology, Biomarkers & Preention</i> , 1998 , 7, 505-514						
	BQ	Velculescu, V.E. et al., "Serial analysis of gene expression" Science, 1995, 270, 484-487						
	BP	Traber, et al., "Intestine-Specific gene transcription", Annu Rev. Physiol, 1996, 58, 275-297						
·	BO Tamai, Y. et al., "Colonic hamartoma development by anomalous duplication in Cdx2 knockout mice", Cancer, 1999, 59, 2965-2970							
	OTHE	CR DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.	.)			
		Department of Commerce at and Trademark Office	Filing Date March 27, 2001	Group 1645	600/290	2002		
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